

Date of Approval: Dec 28

**FREEDOM OF INFORMATION SUMMARY**

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

**NADA 112-051**

**LEVASOLE Soluble Drench Powder  
(levamisole hydrochloride)**

“To combine NADA 112-050 for sheep with NADA 112-051 for cattle under NADA 112-051 and to revise the indications to specify genus species of parasites.”

**SPONSORED BY:**

**SCHERING-PLOUGH ANIMAL HEALTH**

## 1. GENERAL INFORMATION

- a. File Number: 112-051
- b. Sponsor: Schering-Plough Animal Health Corp.  
1095 Morris Ave.  
Union, NJ 07083  
  
Drug Labeler Code: 000061
- c. Established Name: Levamisole hydrochloride
- d. Proprietary Name: LEVASOLE Soluble Drench Powder
- e. Dosage Form: Soluble powder
- f. How Supplied: 0.46 oz (13 g) packet labeled for sheep only; 1.8 oz (52 g) packet and 21.34 oz (605 g) bottle labeled for cattle and sheep
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 11.7 grams in the 0.46 oz packet, 46.8 grams in the 1.8 oz packet, and 544.5 grams in the 21.34 oz bottle
- i. Route of Administration: Oral
- j. Species/Class: Cattle and sheep
- k. Recommended Dosage: Administer as a single dose drench at 8 mg/kg BW.
- l. Pharmacological Category: Anthelmintic
- m. Indications: LEVASOLE (levamisole hydrochloride) is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep:

**SHEEP**

**Stomach Worms:** *Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*

**Intestinal Worms:** *Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*

**Lungworms:** *Dictyocaulus filaria*

**CATTLE**

**Stomach Worms:** *Haemonchus placei*, *Ostertagia ostertagi*, *Trichostrongylus axei*

**Intestinal Worms:** *Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*

**Lungworms:** *Dictyocaulus viviparus*

- n. Effect of Supplement: Provides for combining NADAs 112-050 and 112-051 for sheep and cattle, respectively, with labeling for the 1.8 oz and 21.34 oz containers bearing the indications for both these species and the 0.46 oz container bearing the indications for sheep; only to be marketed under NADA 112-051. The drug formulation of both NADAs is identical and the indications will be the same with the exception that the parasites will be listed according to genus species and that it is effective against only adult nematodes. Additionally, the dose of 8 mg/kg will be inserted into the dosage and administration section.

**2. EFFECTIVENESS**

Effectiveness data were generated in NADAs 42-740 (approved December 4, 1970) and 39-357 (approved October 29, 1969) for sheep and cattle, respectively. NADAs 112-050 (approved October 16, 1979) and 112-051 (October 16, 1979) for sheep and cattle, respectively, referenced the effectiveness data in NADAs 42-740 and 39-357 for their approval. Since the original approvals, the agency has requested that the indications in the labeling for anthelmintic drugs identify the parasites for which the drug is effective to genus species. The labeling of the original approvals identified the parasites to genus only. The original effectiveness studies were reexamined and the appropriate genus species were determined. They have been incorporated into the labeling. No further effectiveness data were required.

**3. TARGET ANIMAL SAFETY**

Target animal safety data were generated in NADAs 42-740 (approved December 4, 1970) and 39-357 (approved October 29, 1969) for sheep and cattle, respectively. NADAs 112-050 (approved October 16, 1979) and 112-051 (October 16, 1979) for sheep and cattle, respectively, referenced the target animal safety data in NADAs 42-740 and 39-357 for their approval. No further target animal safety data were required.

**4. HUMAN SAFETY**

Human safety data were generated in NADAs 42-740 (approved December 4, 1970) and 39-357 (approved October 29, 1969) for sheep and cattle, respectively. NADAs 112-050 (approved October 16, 1979) and 112-051 (October 16, 1979) for sheep and cattle, respectively, referenced human safety data in NADAs 42-740 and 39-357 for their approval. No further human food safety data were required. A tolerance of 0.1 part per million is established for negligible residues of levamisole hydrochloride in the edible tissues of cattle, sheep, and swine.

## 5. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that LEVASOLE Soluble Drench Powder for Sheep and Cattle is safe and effective against certain adult nematode infections, and allow for the combination of NADAs 112-050 and 112-051 so that the product can be marketed with labeling that contains both sheep and cattle indications.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a reevaluation of the effectiveness and safety data in the parent applications.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity.

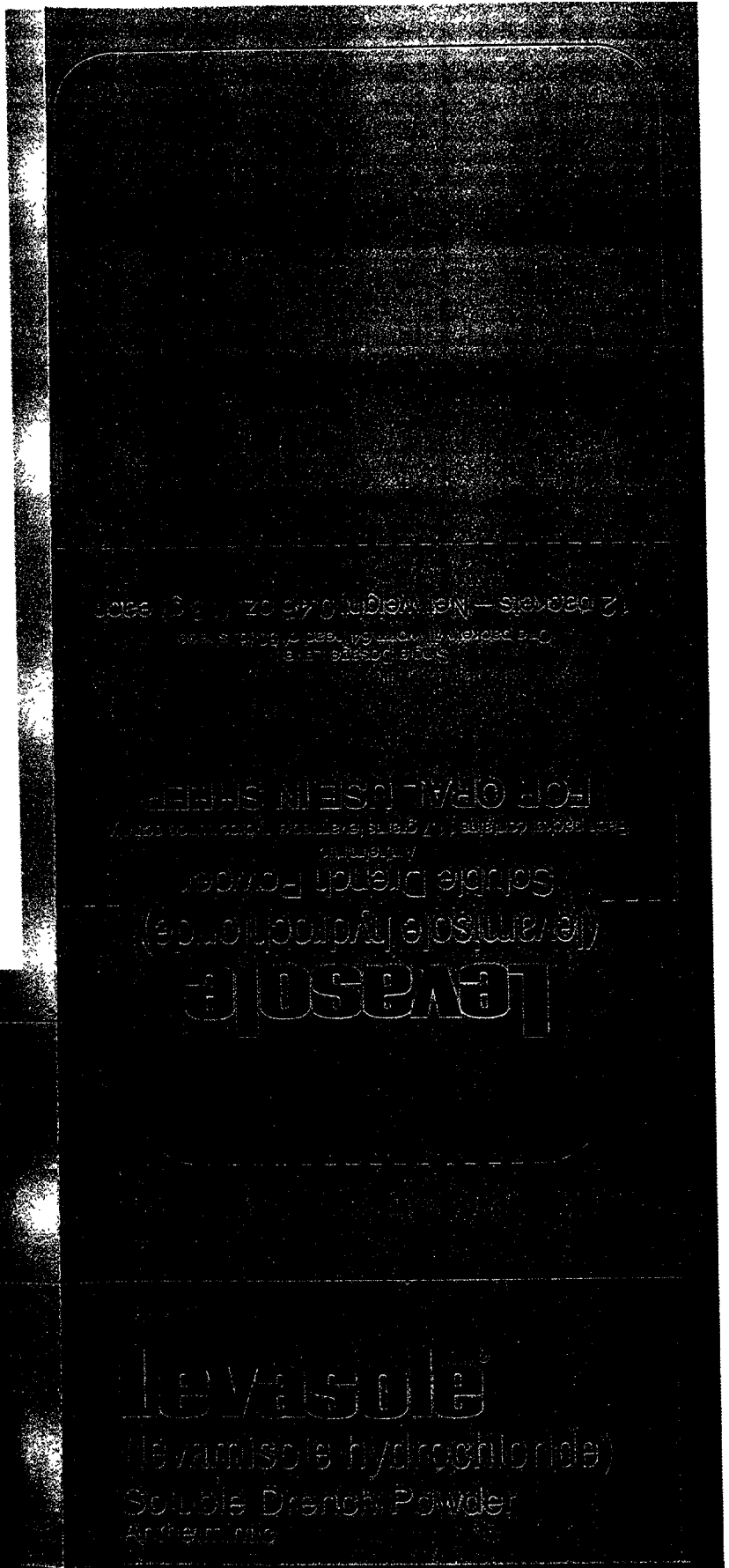
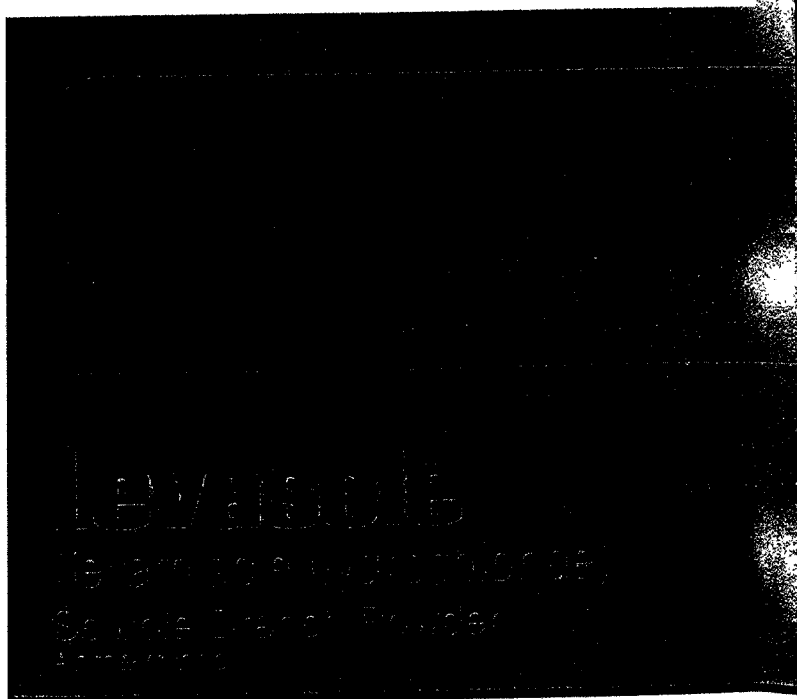
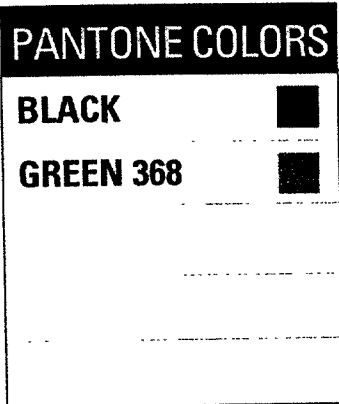
No patent information was submitted with the application.

## 6. ATTACHMENTS:

LEVASOLE Soluble Drench Powder facsimile display carton for the 0.46 oz packets

LEVASOLE Soluble Drench Powder facsimile label for the 0.46 oz and 1.8 oz packets and the 21.34 oz bottle.

1  
OUTPUT @ 100%





**Schering-Plough  
Animal Health**

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Made in Ireland



6/27/03 • RIC#00000000 • PCR# 00000 • 92mm X 11  
Levasole Soluble Drench Powder - 13g display carton • MECHANICAL

**PACKAGING COMPONENT APPROVAL**

SUBMISSION #

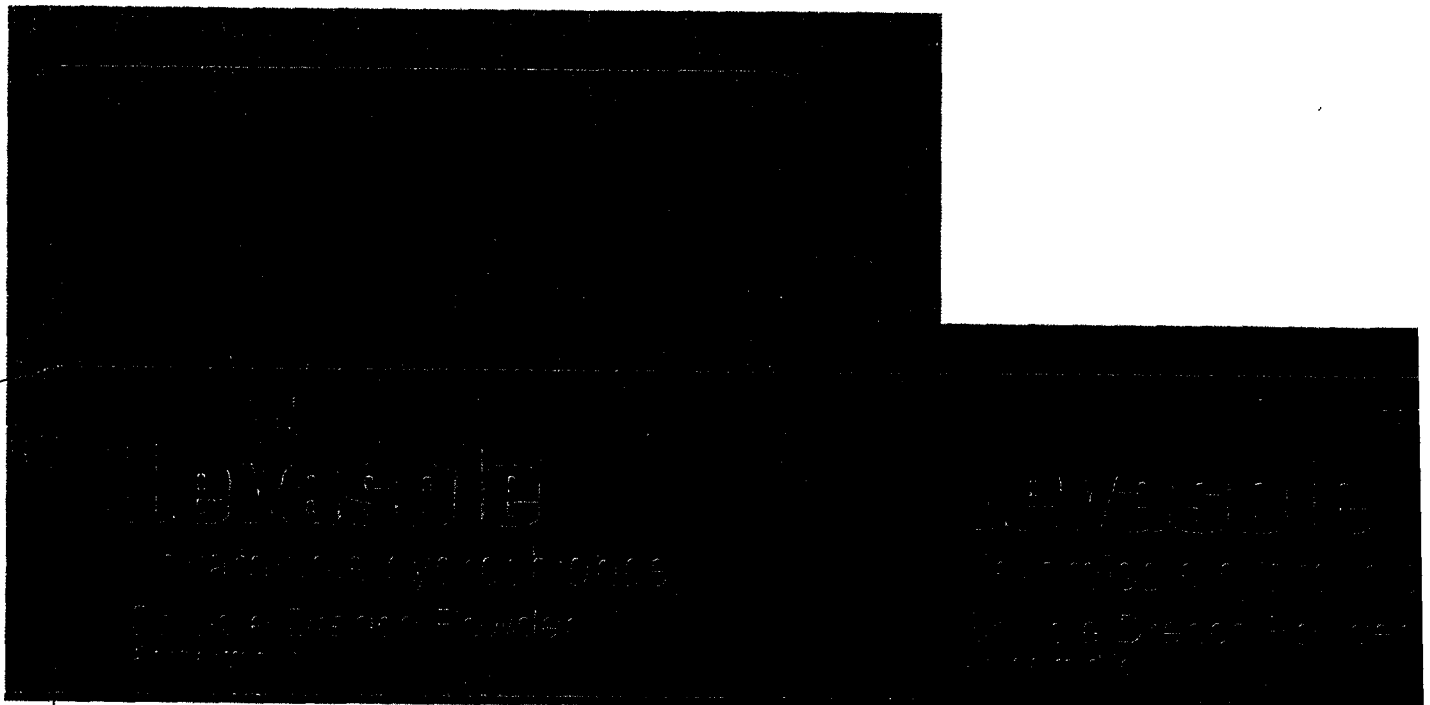
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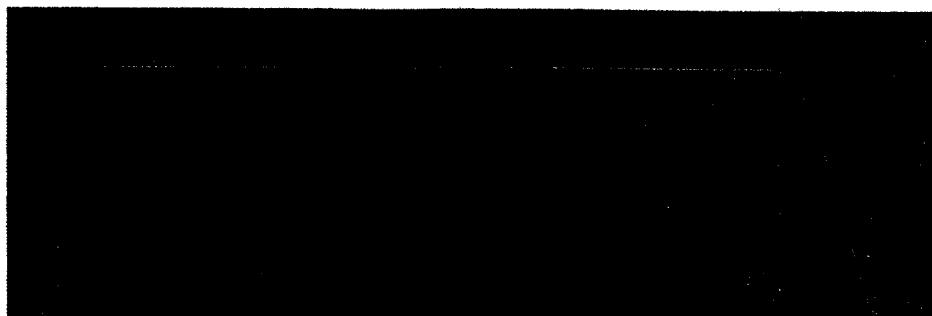
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Animal Health  
Made in Ireland  
NADA #112-051, Approved by FDA

00000000 Rev. 0/00

DIE 4031



7/30/03 • SPAH • RIC#00000000 • PCR# 00000 • 89mm X 216mm  
 Levasole Soluble Drench Powder - 13g pouch • OUTPUT by AF @ 100%



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**INTESTINAL WORMS:** *Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*.

**LUNGWORMS:** *Dictyocaulus filaria*.

**WARNING:** Keep out of reach of children.

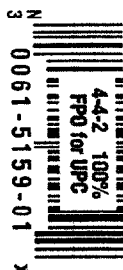


Net Wt. 0.46 oz (13 g)



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NADA #112-051 Approved by FDA



**NOTE:** Careful sheep weight estimates are essential for proper performance of this product. Prepare solutions as needed. However, excess solutions may be stored in clean closed containers up to 90 days without loss of anthelmintic activity. Sheep maintained under conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food animals. Follow recommended dosage carefully.

**PREPARATION OF STANDARD DRENCH SOLUTION**  
For use with standard drench syringe. Place the contents of this packet in a 1 quart (32 fl oz) container. Fill with water and swirl briefly until dissolved. Administer as a single drench at a dose of 8 mg/kg body weight according to the following table:  
**STANDARD DRENCH DOSAGE WILL TREAT ONE PACKET**  

| WEIGHT  | 100 lb    | 150 lb      | 200 lb      |
|---------|-----------|-------------|-------------|
| 50 lb   | 1/2 fl oz | 1 fl oz     | 1 1/2 fl oz |
| 64 head | 1 fl oz   | 1 1/2 fl oz | 2 fl oz     |
| 32 head | 1/2 fl oz | 1 fl oz     | 1 1/2 fl oz |
| 21 head | 1/2 fl oz | 1 fl oz     | 1 1/2 fl oz |
| 16 head | 1/2 fl oz | 1 fl oz     | 1 1/2 fl oz |

**PREPARATION OF CONCENTRATED DRENCH SOLUTION**  
For use with an automatic drenching syringe. Place the contents of this packet in a household measuring container and add water to the 10.9 fl oz level. Swirl briefly to dissolve and then administer at the rate of 1 mL per 10 lb body weight. Refer to the table above for the number of sheep this packet will treat.

## PACKAGING COMPONENT APPROVAL

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## PANTONE COLORS

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**GREEN 368**



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PARACHUTE LUMINESCENT APPROVAL

### DOSAGE AND ADMINISTRATION

**CATTLE-STANDARD DRENCH SOLUTION-** Place the contents of this packet in a 1 quart (32 fl. oz.) container, fill with water; swirl until dissolved. Administer as a single drench dose of 8 mg/kg body weight according to the following table:

| WEIGHT | DRENCH DOSAGE | PACKET WILL TREAT |
|--------|---------------|-------------------|
| 200 lb | 1/2 fl. oz.   | 64 head           |
| 400 lb | 1 fl. oz.     | 32 head           |
| 600 lb | 1 1/2 fl. oz. | 21 head           |
| 800 lb | 2 fl. oz.     | 16 head           |

**SHEEP-STANDARD DRENCH SOLUTION-** Place the contents of this packet in a 1 gallon (128 fl. oz.) container, fill with water; swirl until dissolved. Administer as a single drench at a dose of 8 mg/kg body weight according to the following table:

| WEIGHT | DRENCH DOSAGE | PACKET WILL TREAT |
|--------|---------------|-------------------|
| 50 lb  | 1/2 fl. oz.   | 256 head          |
| 100 lb | 1 fl. oz.     | 128 head          |
| 150 lb | 1 1/2 fl. oz. | 84 head           |
| 200 lb | 2 fl. oz.     | 64 head           |

**CONCENTRATED DRENCH SOLUTION-** For use with 20 mL Automatic Syringe. Place the contents of this packet in a standard household measuring container and add water to the 8 3/4 fl. oz. level; or use the measuring container available from your supplier and add water to the mark. Swirl until dissolved. Give 2 mL (milliliter) per 100 lb body weight. Refer to the table above for the number of cattle this packet will treat.

**CONCENTRATED DRENCH SOLUTION-** For use with 20 mL Automatic Syringe. Place the contents of this packet in a standard household measuring container and add water to the 17 1/2 fl. oz. level. Swirl until dissolved. Give 2 mL per 50 lb body weight. Refer to the table above for the number of sheep this packet will treat.

**NOTE:** Careful weight estimates are essential for proper performance of this product. Prepare solutions as needed. However, excess solutions may be stored in clean closed containers up to 90 days without loss of anthelmintic activity.

Cattle and Sheep maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

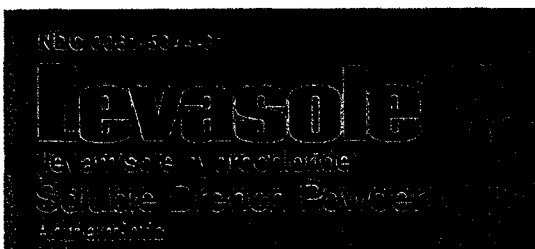
Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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Schering-Plough Animal Health  
Made in Ireland.  
NADA #112-051, Approved by FDA.  
DIRECTIONS  
DIRECTIONS LABEL



Each packet contains 46.8 grams of levamisole hydrochloride activity.

### FOR ORAL USE IN CATTLE AND SHEEP

Administer as a standard drench with standard drench syringe or administer as a concentrated drench solution with an automatic drenching syringe.

**INDICATIONS:** LEVASOLE (levamisole hydrochloride) is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep:

#### SHEEP:

**STOMACH WORMS:** *Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*.

**INTESTINAL WORMS:** *Trichostrongylus colubriformis*, *Cooperia curtipisci*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*.

**LUNGWORMS:** *Dictyocaulus filaria*.

#### CATTLE:

**STOMACH WORMS:** *Haemonchus placei*, *Trichostrongylus axei*, *Ostertagia ostertagi*.

**INTESTINAL WORMS:** *Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*.

**LUNGWORMS:** *Dictyocaulus viviparus*.

**WARNING:** Keep out of reach of children.

Net Wt 1.8 oz (52 g)



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control of parasites.

Consult your veterinarian for assistance in the diagnosis, treatment, and

before using in severely debilitated animals.

be consulted. Follow recommended dosage carefully. Consult your veterinarian

disappear within a few hours. If this condition persists, a veterinarian should

**CAUTION:** Muzzle foam may be observed. However, this reaction will

residues in milk, do not administer to dairy animals of breeding age.

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food.

Do not administer to sheep within 72 hours of slaughter for food. To prevent

may require retreatment within 2 to 4 weeks after the first treatment.

Cattle and Sheep maintained under conditions of constant helminth exposure

in clean closed containers up to 90 days without loss of anthelmintic activity.

**NOTE:** Careful weight estimates are essential for proper performance of this

product. Prepare solutions as needed. However, excess solutions may be stored

of cattle this packet will treat.

Refer to the table above for the number

packet will treat.

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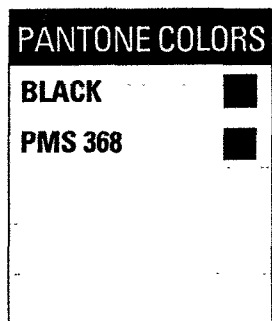
packet will treat.

7/30/03 • LEVASOLE POUCH

RIC# 00000000 • PCR #00000

114mm x 330mm

OUTPUT @ 100% BY AF



HOLDING LINE  
DOES NOT PRINT

### PACKAGING COMPONENT APPROVAL

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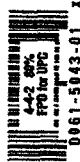
Net Wt. 21.34 oz (1.3 lb)  
(605 g)



Schering-Plough Animal Health

Schering-Plough Animal Health Corp.  
Union, NJ 07083  
Made in Ireland

NADA #112-051, Approved by FDA.



hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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### PACKAGING COMPONENT APPROVAL

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### PANTONE COLORS

BLACK



GREEN 368



### EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK.

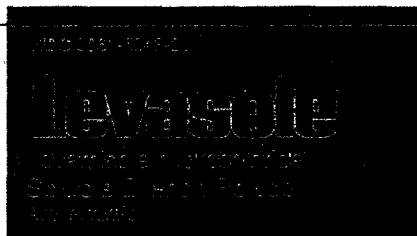
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7/30/03 • SPAH • LEVASOLE BOTTLE LABEL  
• RIC# 00000000 • PCR# 00000 • 143mm x 127mm • OUTPUT BY AF



**Cattle and Sheep Dewormer For Oral Use**

This bottle contains 544.5 grams of levamisole hydrochloride activity.  
**INDICATIONS:** LEVASOLE (levamisole hydrochloride) is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep:

**SHEEP:**

**STOMACH WORMS:** *Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*.

**INTESTINAL WORMS:** *Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovis*.

**LUNGWORMS:** *Dictyocaulus filaria*.

**CATTLE:**

**STOMACH WORMS:** *Haemonchus placei*, *Trichostrongylus axei*, *Ostertagia ostertagi*.

**INTESTINAL WORMS:** *Trichostrongylus longispiculus*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*.

**LUNGWORMS:** *Dictyocaulus viviparus*.



Net Wt. 21.34 oz (1.3 lb)  
(605 g)



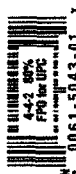
Schering-Plough Animal Health

Schering-Plough Animal Health Corp

Kenilworth, NJ 07033

Made in Ireland

NADA #112-051, Approved by FDA.



**DOSAGE AND ADMINISTRATION:** When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl to mix thoroughly before using. If any solution is left over it may be stored for up to 3 months in this tightly capped bottle. Shake well before using.

**DATE WATER**

**WAS ADDED**

**TO THIS BOTTLE** Month Day Year

Administer as a single drench at a dose of 8 mg/kg body weight:

**CATTLE** – 2 mL per 100 lb body weight

| Weight   | Drench Dosage | Bottle Will Treat |
|----------|---------------|-------------------|
| 100 lb   | 2 mL          | 1,500 head        |
| 300 lb   | 6 mL          | 500 head          |
| 500 lb   | 10 mL         | 300 head          |
| 700 lb   | 14 mL         | 214 head          |
| 1,000 lb | 20 mL         | 150 head          |

**SHEEP** – 1 mL per 50 lb body weight

| Weight | Drench Dosage | Bottle Will Treat |
|--------|---------------|-------------------|
| 50 lb  | 1 mL          | 3,000 head        |
| 100 lb | 2 mL          | 1,500 head        |
| 150 lb | 3 mL          | 1,000 head        |
| 200 lb | 4 mL          | 750 head          |

**NOTE:** Careful weight estimates are essential for proper performance of this product.

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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**PACKAGING COMPONENT APPROVAL**

SUBMISSION #

PANTONE COLORS

EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK.

APPROVED NOT APPROVED

NATF